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PATENT
Customer No. 22,852
Attorney Docket No. 5049.0006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Hans HALLSTADIUS et al.) Group Art Unit: 4112
Serial No.: 10/568,086) Examiner: Marjorie Ellen CHRISTIAN
Filed: February 13, 2006) Confirmation No.: 7479
For: AN APPARATUS, A SYSTEM AND)
A METHOD RELATING TO)
HEMODIALYSIS,)
HEMODIAFILTRATION,)
HEMOFILTRATION OR)
PERITONEAL DIALYSIS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement set forth in an Office Action dated May 7, 2008, the Examiner required restriction under 35 U.S.C. § 121 between:

Group I - Claims 1-15, allegedly drawn to an apparatus for measuring an optically active substance in dialysis and/or infusion fluid.

Group II - Claims 16-17, allegedly drawn to method for measuring an optically active substance in a fluid through an apparatus for hemodialysis, hemodialfiltration, hemofiltration or peritoneal dialysis.

Applicant provisionally elects to prosecute with traverse, Group I, claims 1-15 allegedly drawn to an apparatus for measuring an optically active substance in dialysis and/or infusion fluid.

In the Office Action, the Examiner asserted that the inventions identified in Groups I and II "are not so linked as to form a single general inventive concept under PCT Rule 13.1." (Office Action at 2.) Applicant respectfully disagrees. Under 37 C.F.R. § 1.475, which governs national stage applications, Groups I and II are one unitary invention. 37 C.F.R. § 1.475 states that:

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(Emphasis added.)

Accordingly, because the apparatus identified in Group I is specifically designed for carrying out the process identified in Group II, these groups of inventions have unity

of invention and should be prosecuted in the same application. Thus, for at least this reason, Applicant respectfully asks the Examiner to withdraw the restriction requirement and to allow prosecution of both Groups I and II in this application.

The Examiner further contends that the "inventions listed as Groups I and II do not relate to a single general inventive concept (*a posteriori*) under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features . . . [because] the common technical feature is measuring the optically active substance in a dialysis and/or infusion fluid using a polarized beam of light. This apparatus cannot be a special technical feature under PCT Rule 13.2 because the apparatus is taught in the prior art." (Office Action at 2.) Applicants disagree.

First, Applicant contends that the Examiner has misstated the special technical feature shared by Groups I and II. Applicant submits that the special technical feature shared by Groups I and II is the measuring of an optically active substance in a dialysis and/or infusion fluid for use in hemodialysis, hemodiafiltration, hemofiltration, or peritoneal dialysis, as required in claims 1 and 16, for example. Second, Applicant submits that the prior art reference cited by the Examiner (U.S. Patent No. 5,457,535 to Schmidtke) does not disclose or suggest an apparatus for hemodialysis, hemodiafiltration, hemofiltration, or peritoneal dialysis having a measurement unit for measuring the concentration of a substance in a dialysis and/or infusion fluid. To the contrary, Schmidtke discloses an apparatus for determining the concentration of an optically active substance in body fluids of a patient and can be used, for example, in connection with an implantable insulin pump (col. 2, lines 36-41). Moreover, the apparatus of Schmidtke is described as being used to determine the content of glucose

in a carrier fluid that may also comprise other polarising substances such as antibiotics or protein molecules (see col. 6, lines 3-33). Accordingly, Schmidtke does not disclose an apparatus for hemodialysis, hemodiafiltration, hemofiltration, or peritoneal dialysis, as required by the inventions of Groups I and II.

Thus, for at least these reasons, Groups I and II share a special technical feature that defines a contribution over the prior art. Accordingly, for this additional reason, Applicants respectfully request that the Examiner withdraw the restriction requirement and allow Applicants to prosecute Groups I and II, including claims 1-27, in this application.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: May 30, 2008

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